Contains Nonbinding Recommendations

Draft Guidance on Ombitasvir; Paritaprevir; Ritonavir; and Dasabuvir Sodium

Active Ingredient: I. Ombitasvir; paritaprevir; ritonavir, and II. Dasabuvir sodium

Dosage Form; Route: Co-packaged tablets; oral

Recommended Studies: Four in vivo studies

I. Ombitasvir; paritaprevir; ritonavir tablets

1. Type of study: Fasting
Design: Single-dose, two-way crossover in vivo
Strength: 12.5 mg ombitasvir; 75 mg paritaprevir; 50 mg ritonavir
Subjects: Healthy males and nonpregnant females, general population
Additional comments: None

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2. Type of study: Fed
Design: Single-dose, two-way crossover in vivo
Strength: 12.5 mg ombitasvir; 75 mg paritaprevir; 50 mg ritonavir
Subjects: Healthy males and nonpregnant females, general population
Additional comments: None

II. Dasabuvir sodium tablets

1. Type of study: Fasting
Design: Single-dose, two-way crossover in vivo
Strength: EQ 250 mg dasabuvir
Subjects: Healthy males and nonpregnant females, general population
Additional comments: None

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2. Type of study: Fed
Design: Single-dose, two-way crossover in vivo
Strength: EQ 250 mg dasabuvir
Subjects: Healthy males and nonpregnant females, general population
Additional comments: None

Analytes to measure (in appropriate biological fluid): Ombitasvir; paritaprevir; ritonavir; and dasabuvir in plasma

Bioequivalence based on (90% CI): Ombitasvir; paritaprevir; ritonavir; and dasabuvir

Waiver request of in vivo testing: Not applicable

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods Web site, available to the public at the following location: http://www.accessdata.fda.gov/scripts/cder/dissolution/. Conduct comparative dissolution testing on 12 dosage units each of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).